Clinical evaluation of the Articulinx device for the carpometacarpal joint.

Published: 18-04-2011
Last updated: 27-04-2024

To confirm the safety of the Articulinx ICC by evaluating device- and procedure relates adverse events.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON38020

Source
ToetsingOnline

Brief title
Articulinx CMC study

Condition

- Joint disorders

Synonym
Rizarthrosis, thumb arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Articulinx Inc.
Source(s) of monetary or material Support: Articulinx

Intervention

Keyword: Arthroplasty, Articulinx, CMC, Interpositional

Outcome measures

Primary outcome

Incidence of device- and procedure-related adverse events intra-operatively,

and through two years follow-up.

Average CMC-I joint pain score post-procedure compared to pre-operative

baseline through two years follow-up.

Secondary outcome

Change in pain medication use for CMC-I joint as compared to baseline.

Change in CMC-I joint function post-procedure as compared to baseline.

Change in DASH scores as compared to baseline

Study description

Background summary

A clinical need exists for an early treatment of osteoarthritis of the hand that mitigates pain and restores biomechanics without drug or radical surgery. Articulinx Inc. has developed an alternative treatment for osteoarthritis of the hand. The device is designed to be inserted into the CMC-I joint of the hand, restoring the space between the joint surfaces without disrupting joint architecture or removing supporting bone or soft tissues. A simple minimally invasive procedure is required to insert the implant. The Articulinx device is designed to be implanted earlier in the disease process, allowing a more active lifestyle and potentally reducing or eliminating the need for long term use of prescription medications.

Study objective

To confirm the safety of the Articulinx ICC by evaluating device- and procedure relates adverse events.

Study design

Prospective, non-randomized, non controlled study.

Intervention

Minimally invasive surgical procedure.

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults 35 -75 years old with osteoarthritis of the carpometacarpal (CMC-I) joint. VAS-painscore > 40 at baseline. Subluxation less than 1/3. Patients capable of providing informed

consent.

Exclusion criteria

Significant and affecting pathology of the radial side of the hand and wrist.
Significant osteophytes (> 2 mm) and free floating bodies in CMC-I joint
Rheumatoid and/or Metabolic disorders of the bone.
Prior surgery.
Participating in another study.
Pregnancy and lactation.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-04-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Articulinx Device for the CMC-I joint
Registration:	No

Ethics review

Approved WMO

Date:	18-04-2011

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35822.029.11